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Letter: The GRAPPA-OMERACT initiative to standardise outcomes in Psoriatic Arthritis clinical trials and longitudinal observational studies

Reply to: How are enthesitis, dactylitis and nail involvement measured and reported in recent clinical trials of psoriatic arthritis? A systematic literature review

Dear Sir,

We read with interest the recent letter by Ramiro *et al* reporting data from a systematic literature review on the measurement of enthesitis, dactylitis and nail disease in Psoriatic Arthritis (PsA) clinical trials. The authors highlight the great variety in the outcome measures chosen, cut points and the statistical analysis performed (percentage change, proportion resolved). We are pleased the authors have highlighted this problem and agree with their viewpoints on the clear lack of standardisation of domains and instruments in clinical trials evidenced by the data. Indeed this inconsistency of data reporting has led to significant heterogeneity in both physician assessed and patient reported outcomes particularly in the field of PsA. It is the domains of enthesitis, dactylitis, nail disease as well as skin and axial disease, and the unique impact they subsequently have on physical function and quality of life for patients with PsA, that differentiate psoriatic arthritis from other types of inflammatory arthritis like rheumatoid arthritis (RA). Therefore the accurate assessments of these disease manifestations are of vital importance in drug trials.

In an effort to standardise outcome assessment in PsA the first PsA core domain set to be was developed in 2006 by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Outcome Measures in Rheumatology (OMERACT) working group.[1] This PsA core domain set represented the minimum set of outcomes to be measured in randomized controlled trials (RCTs) and longitudinal observational studies (LOS). A systematic literature review demonstrated increased measurement of the complete PsA core domain set from 23.5% of RCT's in 2006-2010 to 59% of RCTs in 2010–2015. [2] The PsA core domain set was updated, with enhanced patient representation, in 2016 following an extensive program of work.[3] As Ramiro *et al* state the next step is to generate instruments and cut offs for the measurement of these domains; a Core Outcome Measurement Set.

Several international work streams comprise the Core Outcome Measures for Psoriatic Arthritis Clinical Trials (COMPACT) study and have been underway since 2016 to address specifically this problem. The GRAPPA-OMERACT PsA Core Set working group is leading this

work following OMERACT Filter 2.0 methodology.[4] This program of work includes multiple systematic literature reviews, incorporating data up to 2017, in order to synthesise the existing evidence on PsA instrument properties (across RCT and LOS data sources as the authors suggest), a Delphi process with stakeholders (including patients, clinicians, trialists, methodologists and payers), working group meetings and discussion and voting at OMERACT 2018. The resulting Core Outcome Measurement Set will synthesise the evidence and provide guidance for the use of PsA outcome instruments, including not only enthesitis, dactylitis and nail involvement, as discussed by Ramiro *et al*, but all pathophysiological manifestations, life impact and resource use defined in the PsA core domain set.

The OMERACT[5] and Core Outcomes Measurement for Effectiveness Trials (COMET) methodology[6] we are following in the COMPACT study will provide evidence based guidance with international consensus on the best instruments to measure the domains of psoriatic disease and, equally importantly identify current gaps and a research agenda to generate the evidence. In the near future, this will facilitate standardisation of outcomes chosen in clinical trials whilst ensuring that key domains important to both patients and physicians are assessed.

The report by Ramiro *et al* highlights the importance of developing a framework of domains and valid instruments for the consistent assessment of Psoriatic Arthritis in RCT's and observational studies and we suggest herein a robust framework, underway, to achieve this standardisation.

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Laura Coates,

On Behalf of the GRAPPA OMERACT Psoriatic Arthritis working group.

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